

PHARMA*process*

Innovation Forum in Pharmaceutical Process

Comparison between Western and Emerging Plants: OPEX Benchmarking

Nicolas Ponce

28/10/15

www.pharmaprocessforum.com



Agenda

- 1 Introduction to the University of St.Gallen**
- 2 Introduction to St.Gallen's Work on Operational Excellence
- 3 Comparison between Western and Emerging Plants
- 4 Conclusion of the Comparison
- 5 Overview of 2016 Activities



The University of St.Gallen

Institute of Technology Management (ITEM-HSG) and Division of Production Management



University of St.Gallen (HSG)

- Founded in 1898
- 39 institutes and 5 schools (Management, Economics and Political Science, Finance, Law, Humanities and Social Sciences)
- 8,020 students (25% international students), 719 research associates, 93 professors

Institute of Technology Management

- Founded in 1988
- 4 professors for Production Mgmt., Innovation Mgmt., Operations Mgmt. and Entrepreneurship with 40+ research associates

Division of Production Management

- Led by Prof. Dr. Thomas Friedli
- Currently 12 research associates



Division of Production Management at ITEM-HSG

Three competence centers



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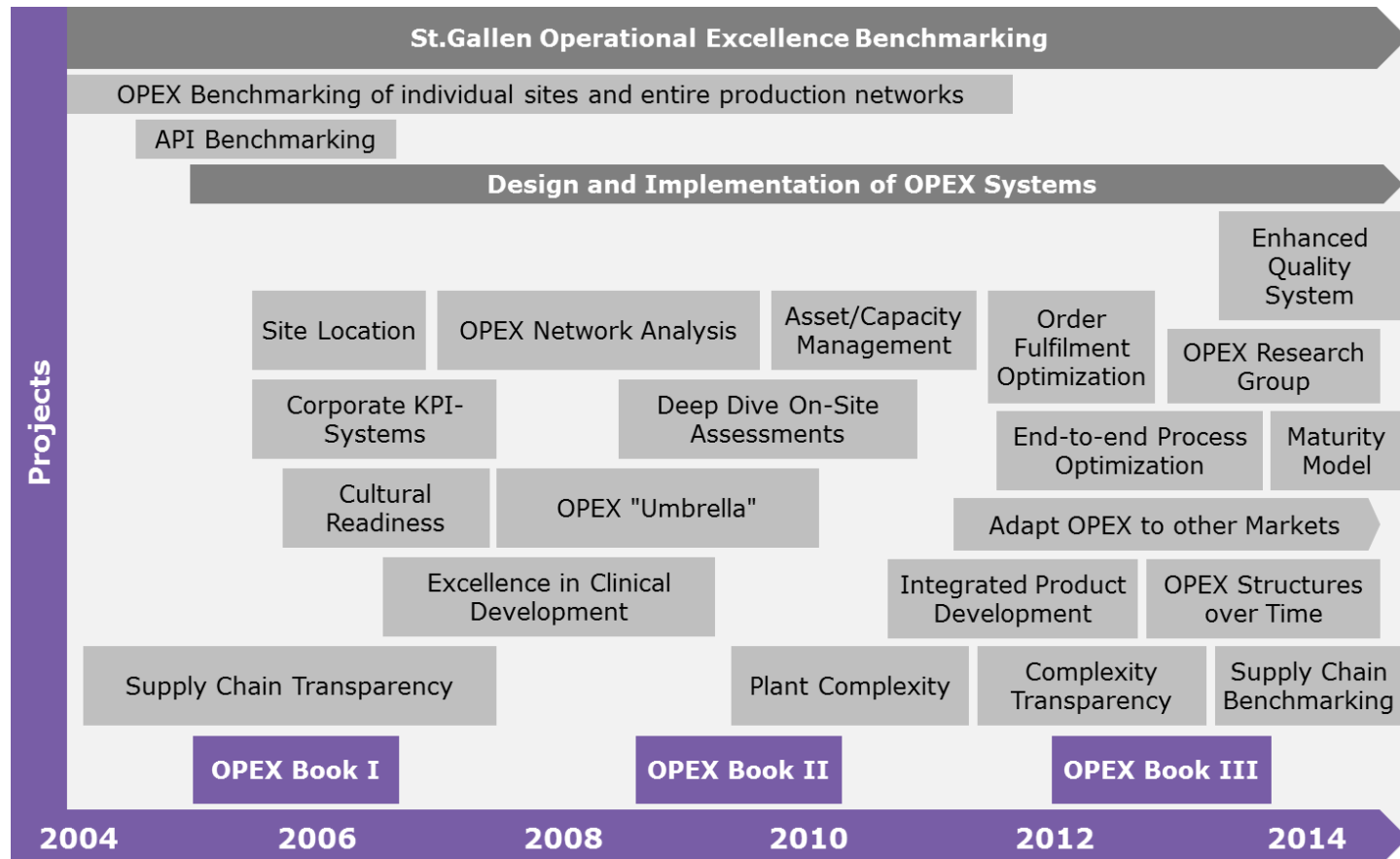
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History of OPEX at the University of St.Gallen

More than 10 years of experience in pharmaceutical Operational Excellence





A Definition of Operational Excellence

The St.Gallen understanding

The ITEM-HSG defines Operational Excellence as a philosophy directing an organization towards continuous improvement!



It is the balanced management of cost, quality and time focusing on the needs of the customer



It comprises structural & behavioural changes to support the needed activities the best way possible



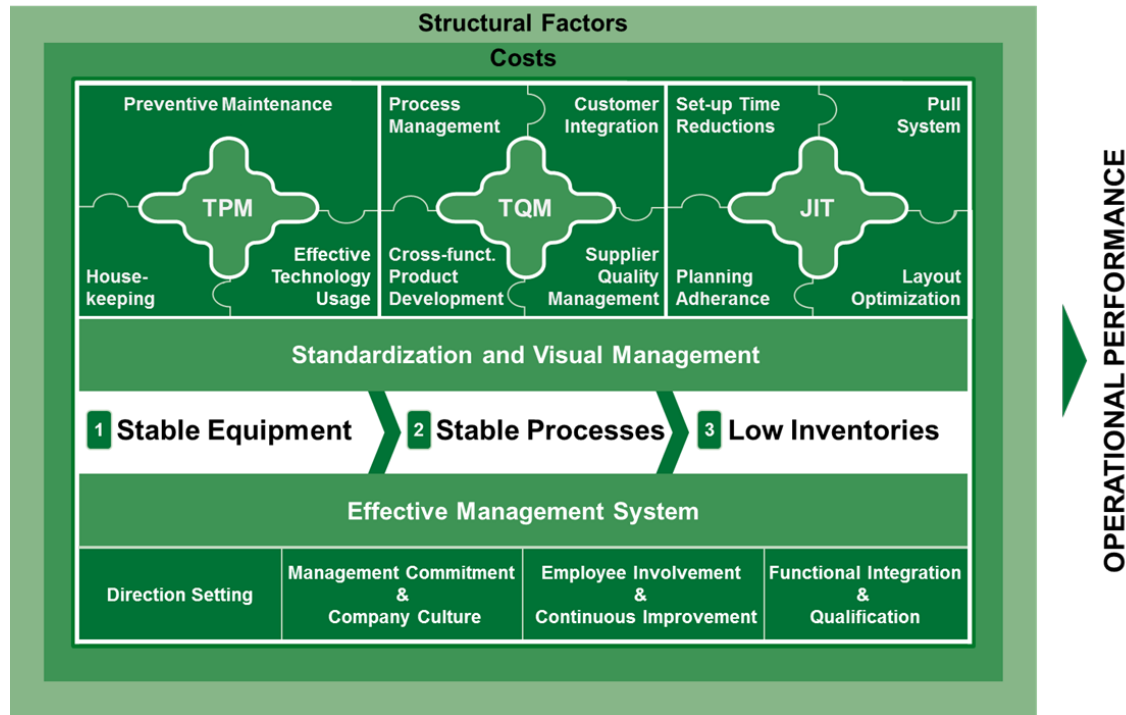
To be sustainable it has to be pushed by Top Management and to be designed to engage every single employee

Operational Excellence is not only about performance, it is also about the way an organization achieves superior performance and about how it continuously improves itself!



The St.Gallen Operational Excellence Model

A framework for thinking about OPEX

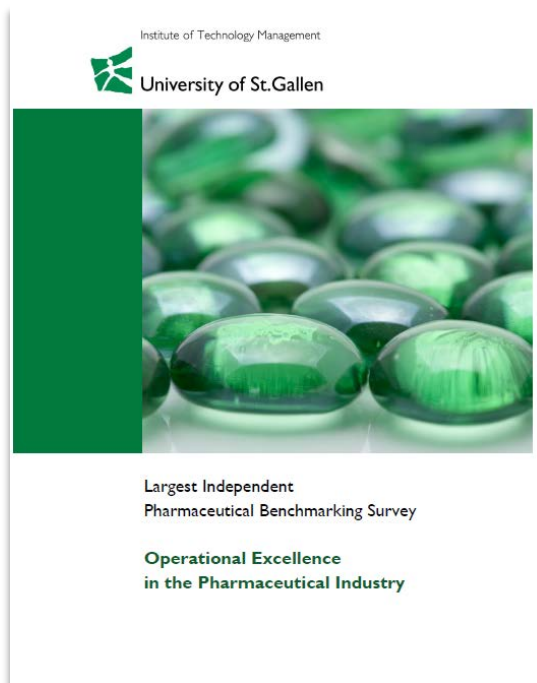


The **St.Gallen Operational Excellence Model** consists of a technical and a social sub-system



The St.Gallen Operational Excellence Benchmarking

Key facts



Industry	Pharmaceutical
Number of Production Sites	315 (Total)*
	230 (Formulation & Packaging)
	61 (API)
	24 (Biotech)
Number of Companies	124 (Total), including 11 companies of the Top 20**
Content – Scope	Enabler Implementation <u>and</u> Performance Metrics (KPIs)
Content – Modules	Total Productive Maintenance (TPM) Total Quality Management (TQM) Just-In-Time (JIT) Effective Management System (EMS)

*Status: October 2015

**According to Pharmaceutical Executive



The St.Gallen Operational Excellence Benchmarking Architecture

Relevant KPIs for the categories:
TPM, TQM, JIT and Effective Management System

KPIs

Implementation of approaches and tools

Enabler

Restrictions by business and
product program

Structural Factors

KPIs cannot be analysed without the consideration of
specific approaches, tools or without understanding the specific
site situation and role



What We Investigate

KPIs (excerpt)

TPM sub-element

- Loading (API, F&P*)
- OEE (API, F&P)
- Set-up and Cleaning (API, F&P)
- Dedicated Equipment (API, F&P)
- Unplanned Maintenance (API, F&P)
- Maintenance Cost/ Overall Cost
- Maintenance Cost/ Conversion Cost

TQM sub-element

- Complaint rate customer
- Yield
- Right First Time
- Rejected Batches
- Scrap Rate
- Release time
- Deviations per batch
- Deviation Closure Time
- Quality Cost/ Overall Cost
- Quality Cost/ Conversion Cost
- Quality Cost per Batch

JIT sub-element

- Days-on-hand
- Service Level (Delivery and Suppliers)
- Forecast Accuracy
- Production Schedule Accuracy
- Production Freeze Period
- Priority Orders
- Material Turns (Raw Material, WIP**, Finished Goods)
- Order Lead Time
- Changeover Time

EMS sub-element

- | | | |
|--------------------------|------------------------|--------------------------|
| ▪ Group Work | ▪ Training Days | ▪ Level of Qualification |
| ▪ Functional Integration | ▪ Employee Suggestions | ▪ Level of Safety |

*F&P: Formulation & Packaging

**WIP: Work-in-progress



What We Investigate

Enabler (excerpt)

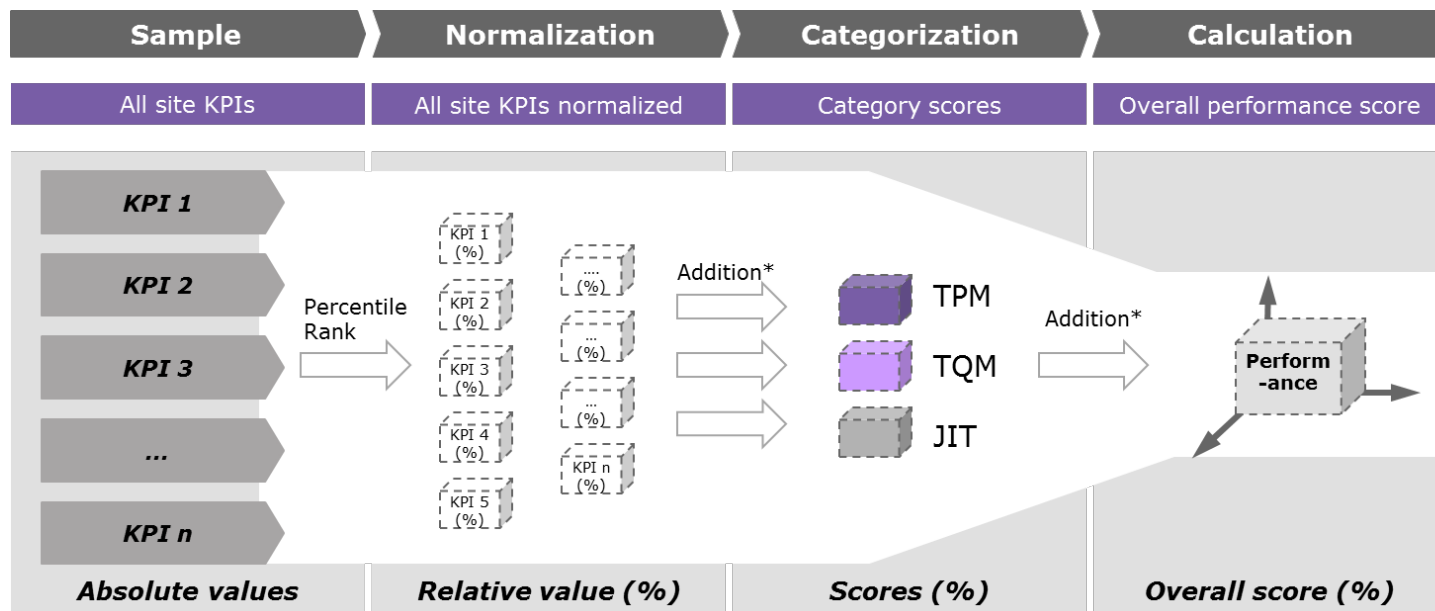
Preventive maintenance	The statement applies to our plant...				
	Not at all	Partially	Completely		Don` t know
We have a formal program for maintaining our machines and equipment.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maintenance plans and checklists are posted closely to our machines and maintenance jobs are documented.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
We emphasize good maintenance as a strategy for increasing quality and planning for compliance.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
All potential bottleneck machines are identified and supplied with additional spare parts.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
We continuously optimize our maintenance program based on a dedicated failure analysis.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Our maintenance department focuses on assisting machine operators perform their own preventive maintenance.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Our machine operators are actively involved into the decision making process when we decide to buy new machines.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Our machines are mainly maintained internally. We try to avoid external maintenance service as far as possible.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The **enabler implementation** is based on a **self-assessment**: A Likert scale from 1 (not at all) to 5 (completely) is provided for each enabler



The St.Gallen Operational Excellence Benchmarking

Performance calculation



Balanced approach for the performance calculation: Consideration of a variety of KPIs to capture the performance holistically



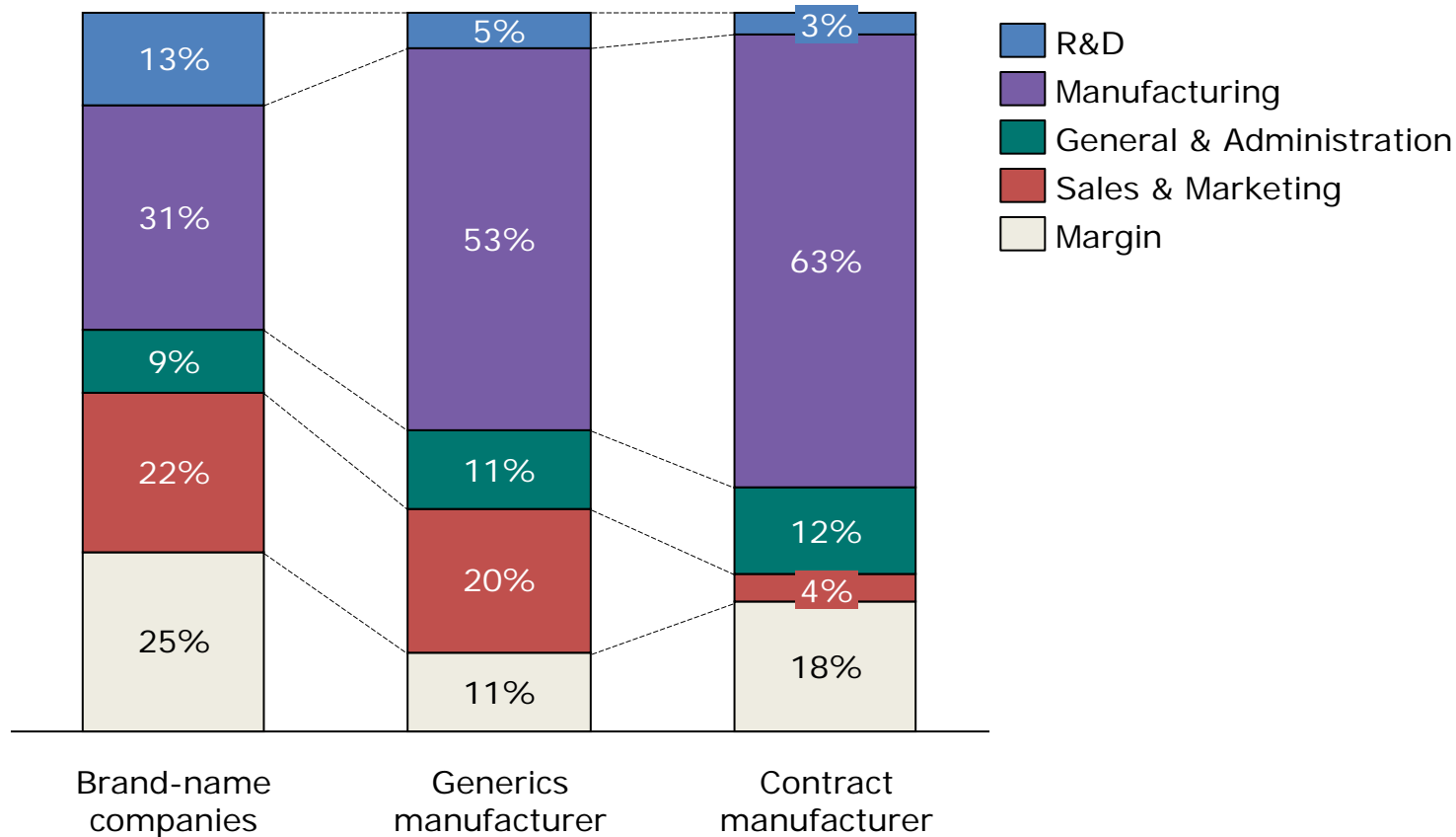
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Motivation for Operational Excellence

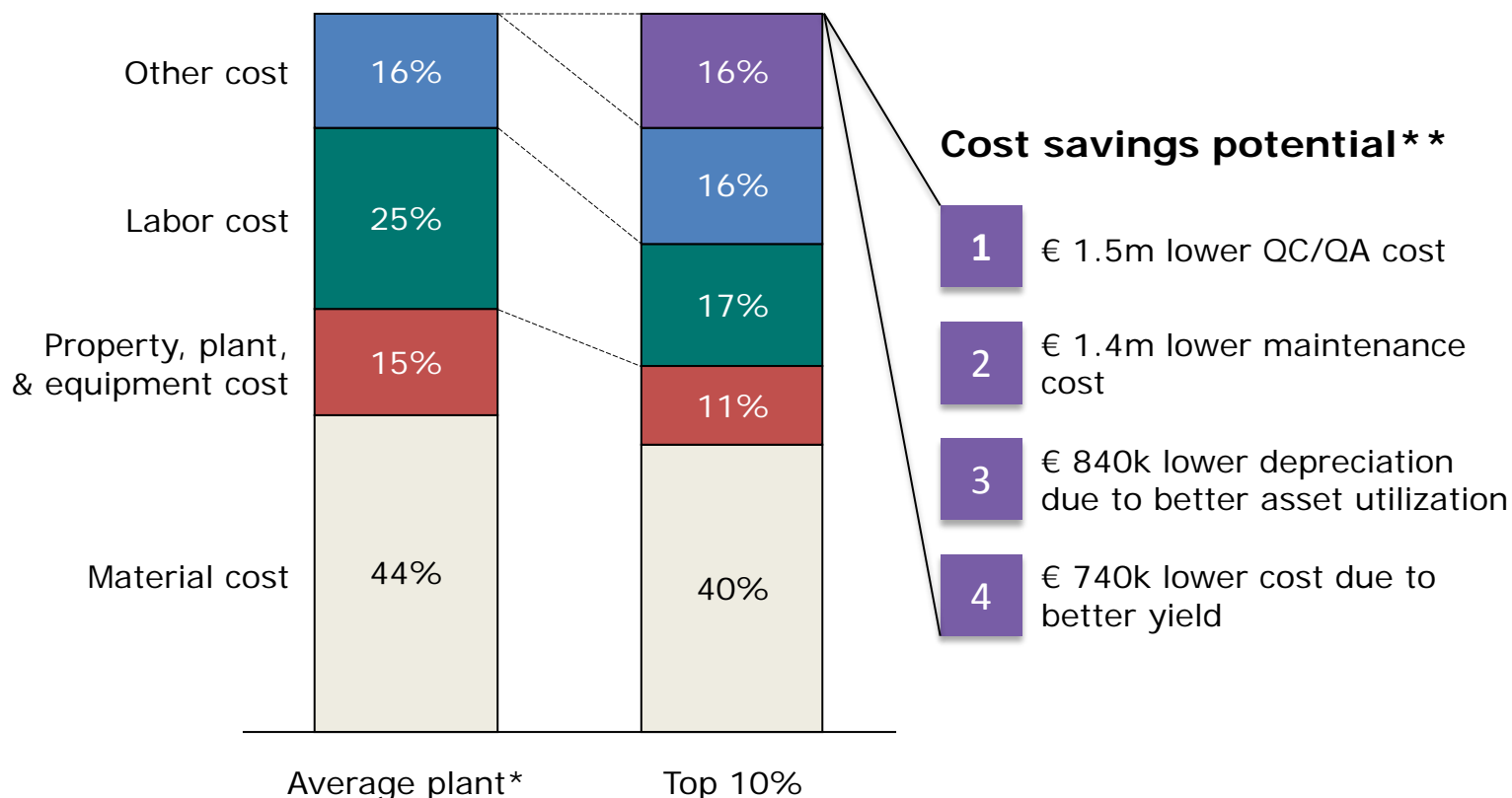
COGS – The cost of goods sold as major part of the overall cost





Motivation for Operational Excellence

The potential for pharmaceutical companies



*100% = € 40m overall cost

**Average cost saving potential of € 6.4 million



Classification of Emerging Markets

Emerging Market is used as an umbrella buzz word with various definitions

- The term emerging market was coined by economists at the International Finance Corporation in 1981
- Commonly applied and colloquial classification criteria are abundant and have become ubiquitous in foreign policy and trade debates, organizations' annual reports, and media
- These criteria can usually be assigned to one of the three categories poverty, capital markets or growth potential:

Category	Criteria
Poverty	<ul style="list-style-type: none">■ Low- or middle-income country■ Low average living standards■ Not industrialized
Capital market	<ul style="list-style-type: none">■ Low market capitalization relative to GDP■ Low stock market turnover and few listed stocks
Growth potential	<ul style="list-style-type: none">■ Economic liberalization■ Open to foreign investment■ Recent economic growth



Classification of Emerging Markets

Definition for this comparison

Following HOSKISSON ET AL. and the Development Policy and Analysis Division of the United Nations, an emerging market falls in one of the two groups of either developing countries or economies in transition

Developing countries

North Africa

Sub-Saharan Africa

East Asia

South Asia

West Asia

Mexico and Central America

South America

Caribbean

Small island developing States

Economies in transition

South-Eastern Europe

Commonwealth of Independent States

Implications

- Emerging markets are widespread over the globe and exist in almost every geographic region!
- The level of economic development between emerging markets differs on a broad bandwidth and constitutes different conditions for companies having business activities there!
- Large emerging markets are heterogeneous countries, i.e. culture and economic prosperity of regions are not congruent within the same market!



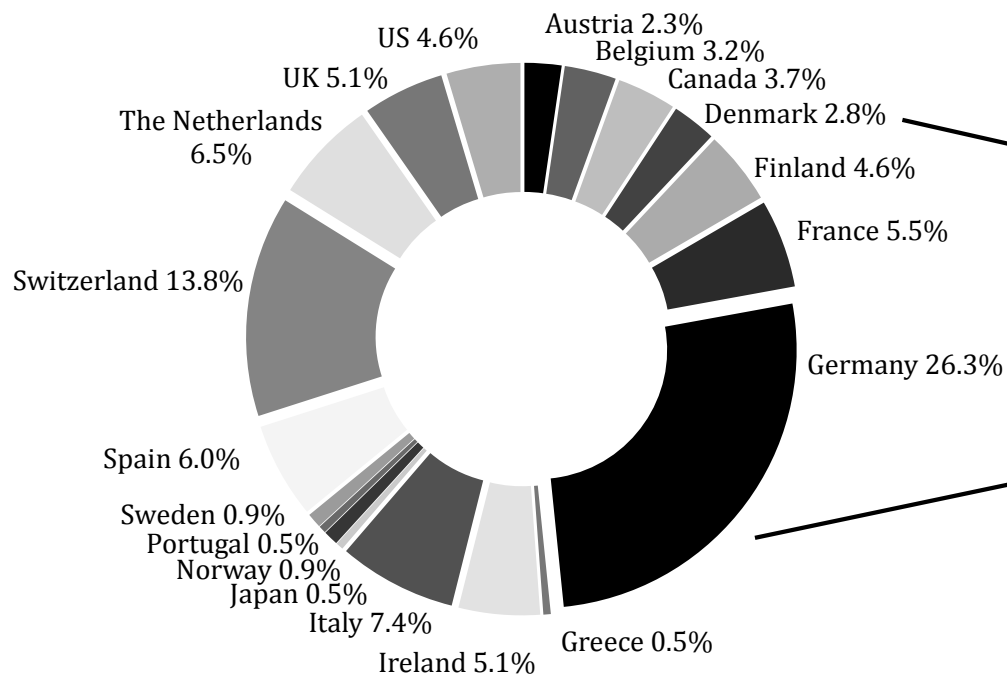
Building the Data Samples

Altogether the chosen data sets were divided into four samples

- The quantitative data used for this comparison stems from the St.Gallen Operational Excellence Benchmarking
- Under consideration of the previously defined classification of emerging markets the chosen data sets were split into:
 - Data sets from advanced countries (**advanced sample**, n=217)
 - Data sets from emerging countries (**emerging sample**, n=37)
- Taking into account only the data sets from advanced countries a further sample was created, comprising only the ten best performing manufacturing sites (**top-10 sample**, n=10)
- In order to assess the differences between pharmaceutical manufacturing sites of multinational organizations and domestic manufacturers the emerging sample was split in these two groups:
 - Data sets from multinationals (**offshore sample**, n=18)
 - Data sets from domestic manufacturers (**domestic sample**, n=19)



Geographic Distribution of the advanced & top-10 Sample n=217



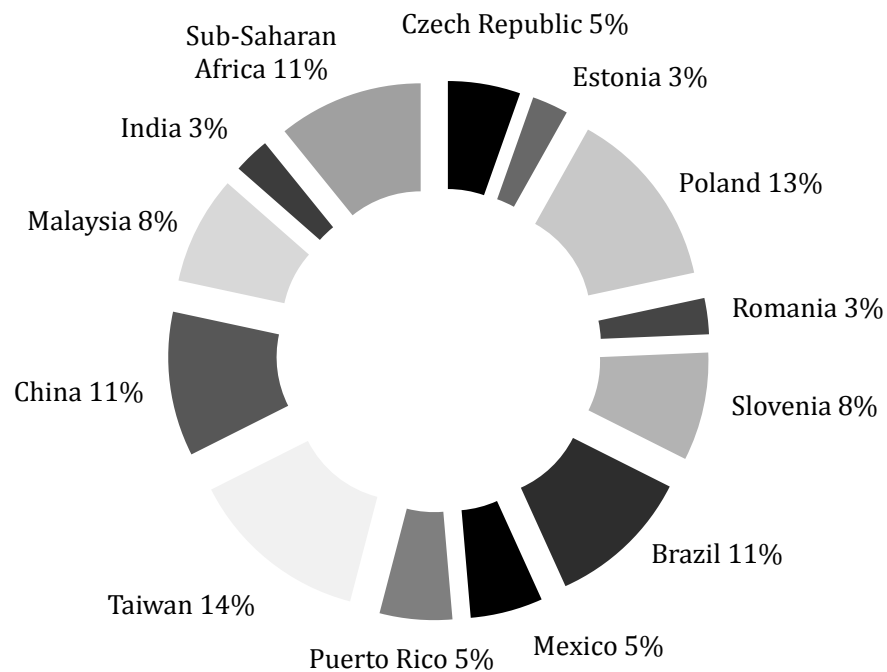
Top-10

Belgium	10%
Canada	10%
Germany	30%
Italy	20%
The Netherlands	10%
US	20%



Geographic Distribution of the emerging Sample

n=37





Structural Factors Comparison

Size of manufacturing site

Pharmaceutical manufacturing sites in both the advanced and emerging sample are of different sizes (employee counts) indicating that implementing Operational Excellence is relevant for companies regardless their size and geographic region

Number of employees	advanced n=217	emerging n=37
< 100	18%	8%
100-300	41%	26%
301-500	23%	38%
501-1.000	13%	21%
> 1.000	5%	7%



Structural Factors Comparison

Production structure

In both samples the production structure of the majority of manufacturing sites focus on at least two dosage forms (mixed sites) instead of only manufacturing a single dosage form

Production structure	advanced n=217	emerging n=37
API	16%	23%
Solids	21%	16%
Semi Solids	1%	3%
Liquids	3%	0%
Sterile Liquids	7%	6%
Mixed	52%	52%



Structural Factors Comparison

Business model

Differences between the samples are observable in the underlying business model. The majority of domestic manufacturers produces generics whereas multinationals in emerging markets and sites in advanced countries are predominantly research driven and manufacture IP-protected drugs

Business model	advanced n=217	offshore n=18	domestic n=19
Research driven	47%	50%	27%
Generics	30%	39%	68%
Contract manufacturer	23%	11%	5%



Enabler Implementation Comparison

Technical system

Sub-system	top-10 n=10	advanced n=217	offshore n=18	domestic n=19
TPM				
Preventive maintenance	79%	75%	75%	75%
Technology assessment & usage	64%	60%	60%	61%
Housekeeping	87%	83%	84%	82%
TQM				
Process management	73%	72%	72%	73%
Cross-functional product develop.	76%	68%	73%	63%
Customer integration	75%	73%	73%	73%
Supplier quality management	75%	69%	69%	68%
JIT				
Setup time reduction	69%	63%	60%	66%
Pull production	62%	49%	47%	51%
Layout optimization	73%	64%	63%	66%
Planning adherence	76%	71%	71%	71%

■ x > 75%

■ 75% > x > 65%

■ 65% > x > 60%

■ x < 60%




Enabler Implementation Comparison

Social system and basic elements

Sub-system	top-10 n=10	advanced n=217	offshore n=18	domestic n=19
EMS				
Direction setting	88%	80%	83%	77%
Management commitment & company culture	76%	73%	74%	72%
Employee involvement & continuous improvement	71%	67%	70%	64%
Functional integration & qualification	71%	66%	64%	67%
Basic elements				
Standardization	69%	73%	71%	76%
Visualization	56%	60%	62%	59%

 $x > 75\%$

 $75\% > x > 65\%$

 $65\% > x > 60\%$

 $x < 60\%$



Enabler Implementation Comparison

Interim conclusion

- Reviewing the enabler implementation comparison results it appears that there is only little variety at implementation of OPEX practices between domestic and offshore sites
- Even more surprising is that there is also little difference between these two samples and the cluster representing manufacturing sites in advanced markets
- Apart from the basic elements sites of the top-10 sample indicate an at least as high or even higher implementation level of OPEX practices than offshore and domestic emerging market sites
- Generally, there are two explanations for these results:
 1. The enabler implementation is based on a self-assessment and consequently the benchmarking results depend to a large extent on the knowledge and maturity level of the participating site
 2. Sites which participate twice at the benchmarking usually are more self-critical the second time as they are aware that they can do more with regard to the activities stated in the OPEX benchmarking questionnaire



Operational Performance Comparison

Production schedule accuracy

Comparing the samples it becomes evident that domestic sites have the lowest level of production schedule accuracy. Noteworthy, firstly, their counterparts, namely offshore sites of multinational organizations, provide a higher accuracy which is close to the top-10 manufacturing sites. Secondly, the average pharmaceutical site in an advanced market has a low production schedule accuracy that is akin to domestic sites. This allows the conclusion that it is less the emerging market per se that is the driver of low production schedule accuracy. Rather it is the capability of the site's management to provide the production department with an adequate level of stability

top-10 n=10	advanced n=217	offshore n=18	domestic n=19
96.2%	85.3%	92.2%	81.9%



Operational Performance Comparison

Production freeze period [days]*

A means to create planning stability is the introduction of a production freeze. The comparison shows that it is only the top-10 sites which positively set themselves apart from the other samples providing their customers with significantly higher production flexibility. Though a shorter production freeze period is less prone to external shocks and thus lowers the probability of disruptions it requires a tightly controlled supply chain as it does not allow long delivery times for supplies. Thus, the accuracy of the production schedule is not directly influenced by the length of the freezing period but rather by how the site adheres to it

top-10 n=10	advanced n=217	offshore n=18	domestic n=19
13.9	21.9	26.9	21.3



Operational Performance Comparison

Percentage of priority orders*

Adherence to the schedule is affected by a belated acceptance and inclusion of additional or substituted orders. These orders are measured by the proportion of priority orders which deviates to a large extent between the illustrated samples. It is apparent that such disturbance of the planned system has negative effects on its stability and on the accuracy of the production schedule

top-10 n=10	advanced n=217	offshore n=18	domestic n=19
10.4%	10.8%	14.5%	41.1%



Operational Performance Comparison

Percentage of dedicated equipment

The availability of equipment that is dedicated to a single product alleviates scheduling of manufacturing machinery. Less changeovers and higher planning flexibility also affect the accuracy of the production schedule in a positive way. Domestic sites have the lowest percentage of dedicated equipment among the samples. On the one hand this might stem from fewer resources of these sites that do not allow investments in a broad machine portfolio. On the other hand the manufacturers' product portfolio in emerging markets is less characterized by high volume and therefore does less justify equipment solely dedicated to one product

	top-10 n=10	advanced n=217	offshore n=18	domestic n=19
Formulation	46.7%	24.8%	24.3%	10.9%
Packaging	54.3%	22.1%	29.9%	5.9%



Operational Performance Comparison

Production lead time [days]

On average, domestic pharmaceutical manufacturers in emerging markets have longer production lead times than offshore sites of multinational organizations or sites in advanced economies. The comparatively low production lead time of the top-10 sites is seen as an indicator for their efforts in implementing Operational Excellence at their sites. On the contrary, domestic sites have the samples' shortest lead time for quality tasks like validations, batch review, and final release. This result should be viewed with caution, since the benchmarking doesn't provide any information about the underlying workload and procedures

	top-10 n=10	advanced n=217	offshore n=18	domestic n=19
Manufacturing	6.3	11.2	7.6	16.5
QA/QC	10.7	20.5	18.0	7.5



Operational Performance Comparison

Deviations per batch and deviation closure time [days]

The comparison of the manufacturing sites' process stability exhibits that sites in advanced economies have a better control of their processes than pharmaceutical organizations in emerging markets. Interestingly, this applies whether the site belongs to a Western based multinational company or is a domestic emerging market company. Such low process stability and deviating product quality is seen as a root cause for occasionally poor drug quality. Moreover, it is apparent that the top-10 sites not only have less deviations per batch, but they also need less time to close such deviations. Since there is no value added this constitutes a large potential for waste reduction at pharmaceutical manufacturing sites

	top-10 n=10	advanced n=217	offshore n=18	domestic n=19
Deviations per batch	0.12	0.16	0.33	0.29
Deviation closure time	13.4	26.6	29.3	22.4



Operational Performance Comparison

Service level (delivery)

The highest service level is demonstrated by emerging market offshore sites whereas domestic sites display the lowest level. Since both samples' sites operate in a similar environment such difference can hardly be reduced to poor infrastructure like road conditions. Rather, the KPI covers the dimensions time, quantity and quality (on time in full; OTIF) and thus provides room for improvement in regards to the previously mentioned quality deviations

top-10 n=10	advanced n=217	offshore n=18	domestic n=19
90.1%	91.7%	94.7%	87.6%



Operational Performance Comparison

Functional integration

The level of functional integration – percentage of trained employees who can work on three or more functions – between domestic emerging market sites and multinational offshore sites deviates by more than 15%. Since a high level of functional integration is a result of education and training, this observation reveals that domestic sites are characterized by less purposeful training than their counterparts in and from advanced economies

top-10 n=10	advanced n=217	offshore n=18	domestic n=19
56.0%	45.0%	44.5%	29.5%



Operational Performance Comparison

Interim conclusion

- As the level of enabler implementation indicates the efforts a production site takes to improve its operations, the measurement of respective KPIs provides insights into the site's operational performance
- The comparison of selected KPIs provides mixed findings. Although the implementation level of Operational Excellence practices at domestic emerging market manufacturing sites affirms these sites perform a rather high level of Operational Excellence, such level is not sufficiently reflected in the discussed KPIs
- These findings are in line with the on-site analyses which were conducted by UNIDO and the University of St.Gallen in Kenya and South Africa. The next section provides a brief overview about these OPEX missions which helps to understand the final conclusion of this comparison



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UNIDO & St.Gallen Missions in Kenya and South Africa

Next planned OPEX mission in South Africa on November 9th – 18th

Objective

In a joint project with the United Nations Industrial Development Organization (UNIDO), assessment of the applicability and acceptance of the St.Gallen Operational Excellence (OPEX) model and benchmarking at selected pharmaceutical manufacturers in South Africa

Approach

- 10 days' stay in South Africa (November 2015)
- Several site visits to combine a qualitative on-site perspective to the benchmarking data
- Conference on Operational Excellence with local pharma leaders in South Africa

Deliverables

- Introduction of OPEX to site, production, and quality managers
- OPEX assessment and establishment of a South African data sample
- OPEX Reports (backed-up with impressions from site visits) for participating manufacturing sites

Next steps

- Discussion between UNIDO and the South African Department of Trade & Industry (DIT) to assess the engagement regarding a possible intervention
- Identification of companies that might be interested
- Discussion and development of collaborations with local universities and knowledge centers in South Africa



UNIDO GLOBAL PROJECT: STRENGTHENING THE LOCAL PRODUCTION OF ESSENTIAL MEDICINES IN DEVELOPING COUNTRIES (DCs)

...can increase access to medicines and contribute to economic growth



UNIDO & St.Gallen Missions in Kenya and South Africa Impressions





Barriers to Overcome for Emerging Plants

Existing external and internal barriers in emerging markets

Building on a literature review, the benchmarking results, and the on-site analyses in Kenya and South Africa the following barriers were identified, which hamper the further development towards Excellence

External barriers	Internal barriers
Poor education of employees	Mere focus on lean tools
Government involvement	Missing link to business strategy
Rigid sociocultural system	Poor quality practices
Weak supplier performance	Poor inventory management
	Lack of resources
	Poor employee training
	Lacking understanding of lean
	Short-term thinking
	Management behavior
	Working attitude
	Staff turnover rate



Conclusion of the Comparison

Discrepancy between OPEX enabler implementation and performance

- The comparison results pose a certain discrepancy between the enabler implementation of Operational Excellence practices and the actual site performance assessed by selected KPIs
- On the one hand the indications denote a scarce understanding of Operational Excellence or at least a lack of a decent benchmark for comparing the own site's capabilities as a learning opportunity. Such a possibility of comparison would contribute to a better reflection of own achievements and shortcomings of practice implementations
- On the other hand the comparison of KPIs showed values which are either on the top level of the top-10 manufacturing sites, or far below an industry average. Combined, the divergence of KPIs raises questions that cannot be answered by merely analyzing survey data



Conclusion of the Comparison

Need for a clear guidance on how to holistically implement OPEX initiatives

- In summary, the visited companies in particular, and other domestic pharmaceutical manufacturing sites in emerging markets in general – regardless their status quo and progress within the implementation of selected OPEX concepts – might lack a customized and tailored process as to how to transform their operations towards OPEX
- Emerging markets must not only be distinguished from advanced markets, but different characteristics of these markets also necessitate an individual differentiation of emerging markets from each other
- There are companies that assume emerging markets to function similarly to advanced markets but lagging behind in their development. Some of these companies hold a view that (managerial) concepts that work at home, will also equally work abroad



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St.Gallen OPEX Roadshow 2016

Exchange platform with presentations and workshop sessions on OPEX

Locations

Dublin (Ireland) February 9th

Peking (China) May (t.b.d.)

Peapack-Gladstone,
New Jersey (U.S.) June (t.b.d.)

Barcelona (Spain) t.b.d.

Zurich (Switzerland) September
(t.b.d.)

Agenda

09:00 - 09:15	Introduction & Today's Overview	Prof. Friedli
09:15 - 09:45	Operational Excellence 2016 - What are the "Hot Topics"?	St.Gallen OPEX Team
09:45 - 10:45	Operational Excellence: Implement - Sustain - Develop	Prof. Friedli
10:45 - 11:00	Coffee Break	All
11:00 - 12:00	Operational Excellence in the Pharmaceutical Industry - A Case Collection	St.Gallen OPEX Team
12:00 - 13:00	Lunch	All
13:00 - 14:30	Operational Excellence Case Study - Conduction	Interactive Workshop
14:30 - 15:00	Coffee Break	All
15:00 - 16:00	Operational Excellence Case Study - Discussion	Interactive Workshop
16:00 - 17:00	Deriving Takeaways for the Own Company	St.Gallen OPEX Team
17:00 - 17:15	Wrap-up & Outlook	Prof. Friedli

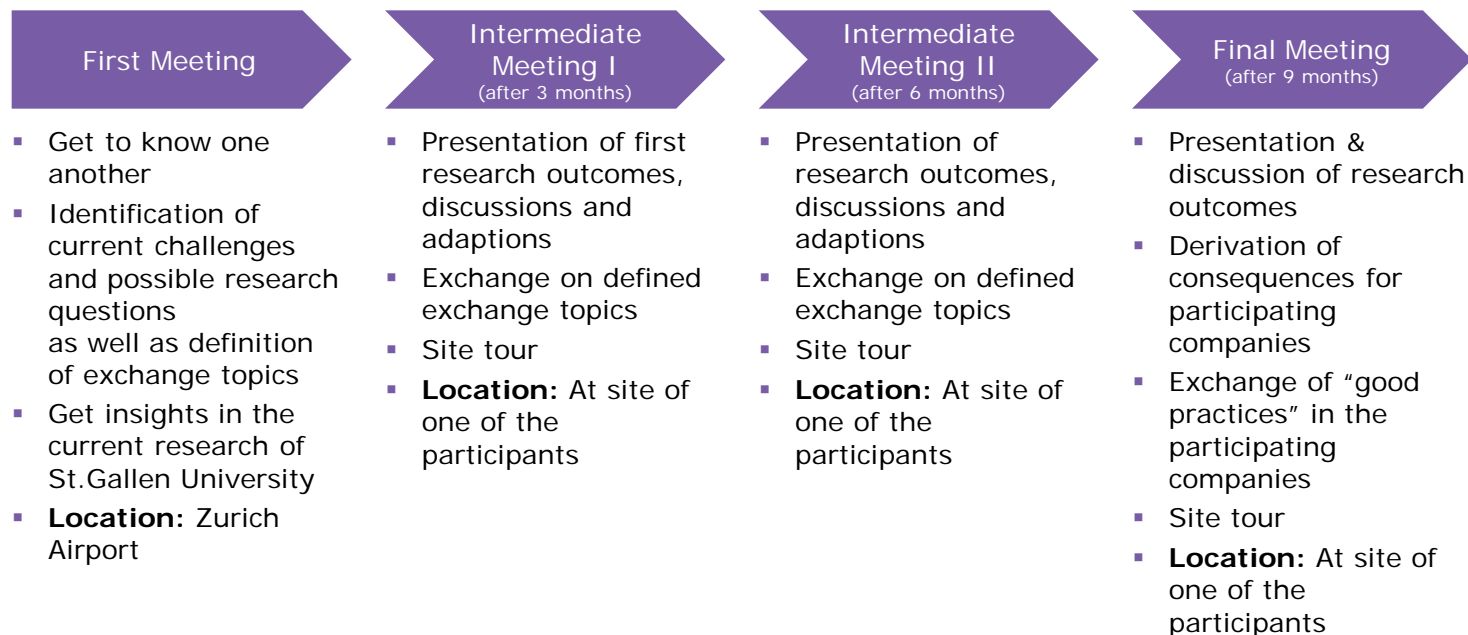
Find more information and sign up on:

<http://opexbenchmarking.com/opex-roadshow-2016/index.php>



St.Gallen OPEX Research Group 2016

Mode of operations



In 2015, the OPEX Research Group comprises 8 companies:
Bayer, Boehringer Ingelheim, Genentech/Roche, Pfizer,
Sandoz, Sanofi, Shire, and Takeda



St.Gallen OPEX Research Group 2016

Member benefits

- Professionally hosted and coordinated platform for exchange, networking, and research on Operational Excellence
- Preparation, moderation, and documentation of meetings by ITEM-HSG
- Mix of discussions, presentations, workshops, and site tour's organized at the sites of the participating companies
- Definition of research fields and access to latest research results from the University of St.Gallen
- Possibility to benchmark and learn OPEX practices against leading organizations and enlarge the network with industry leaders

Terms and conditions of participation:

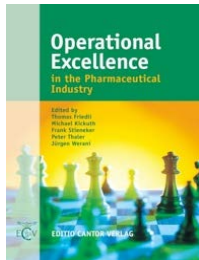
Project duration: 10 months (1-3 people of your company)

Participation fee: USD 15.000 excl. travel expenses



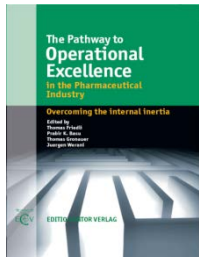
St.Gallen OPEX Books

Combination of theoretical knowledge and practical examples on OPEX



Operational Excellence in the Pharmaceutical Industry

- Detailed overview of the result of the first OPEX Benchmarking conducted by the University of St.Gallen
- Shows the different key issues of setting up an improvement program for operational excellence as well as the status of pharmaceutical production with regard to lean thinking



The Pathway to Operational Excellence in the Pharmaceutical Industry

- The follow-up to our first OPEX Book is bringing together academia's research and companies' experiences in one book
- Leading company representatives describe and explain their OPEX programs in-depth, discuss successful practices, and challenges (e.g. Pfizer, Wyeth, etc.)



Leading Pharmaceutical Operational Excellence

This book presents such leading practices for managing OPEX throughout the pharmaceutical industry. Based on the St.Gallen OPEX Model we describe the current status of OPEX and the future challenges that have to be dealt with. The ample theoretical background is complemented hand-in-hand by case studies contributed by authors from leading pharmaceutical companies like Pfizer, Novartis, Abbott, Amgen, etc.



Thank you very much for your attention!

Q&A

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